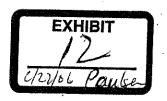
# EXHIBIT 53



## MEDICAID SERVICES

### PRESCRIPTION DRUG PROGRAM

Dorothy Poulsen

Program Officer

December 6, 1999

MT 006626

#### Montana Medicaid Prescription Drug Program

#### **Program Overview**

The Omnibus Budget Reconciliation Acts (OBRA) of 1990 and 1993 defined the current scope and form of Medicaid prescription drug programs. This legislation defines the drug rebate program, specifies drug coverage, requires drug utilization review, and encourages electronic claims processing. Montana Medicaid implemented its drug rebate program in 1991, and implemented both point-of-sale claims processing and the drug utilization review program in September 1994. In the last five years, the program has developed a fully operational prospective and retrospective drug review program, worked with The University of Montana School of Pharmacy to develop a drug formulary, and implemented a prior authorization program.

#### Drug Coverage and Reimbursement

The program covers most legend (prescription) drugs and prescribed over-the-counter aspirin, laxatives, antacids, insulin, and head lice treatments. Drugs must be covered by a manufacturer rebate agreement, and not classified as less-than-effective (DESI) by the Food and Drug Administration. Prescriptions are limited to a 34-day supply or 100 doses, whichever is greater.

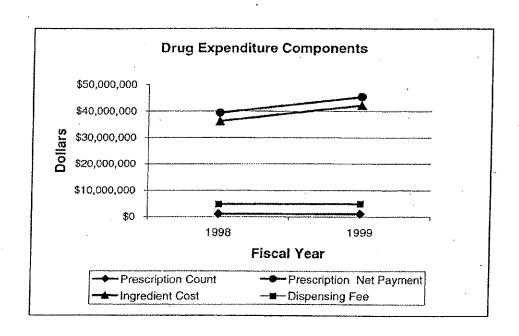
Drugs must be dispensed through an enrolled licensed pharmacy. Currently, approximately 300 pharmacies participate in the Medicaid program. Drugs provided in the physician's office or in hospital are covered outside the prescription drug program. Medicaid recipients pay \$1 for generic and \$2 for brand-name prescriptions.

Reimbursement for prescription drugs has two components: the cost of the drug product and a dispensing fee for the pharmacists' services. Medicaid pays the lessor of : provider's usual and customary charge; the average wholesale price (AWP) less 10% plus a dispensing fee; or the Maximum Allowable Cost (MAC) plus a dispensing fee. The dispensing fee ranges from \$2.00 to \$4.20 with an additional \$0.75 allowed for unit dose prescriptions. Retail pharmacies are assigned a dispensing fee based on the result of a dispensing fee survey, which determines their cost of filling prescriptions. The current maximum dispensing fee of \$4.20 covers between one-fourth and one-half of the cost incurred by pharmacies.

Drug pricing is a prime example of free market capitalism at work. In the United States, manufacturers set the price of their drugs independent of any regulation or guideline. When there is competition, the price of drugs decreases; without competition, the pharmaceutical company charges whatever the market will bear. New medications have patents that preclude direct competition for a number of years and create tremendous profits for the company. The result is a highly profitable industry that performs well on the stock market and has the ability to finance a highly effective lobbying effort both in Congress and in every state legislature. For these reasons, brand-name drugs are relatively expensive.

### **Drug Expenditure Components**

	Prescription		Ingredient	Dispensing	Ingredient	Dispensing
Fiscal Year	Count	Net Payment	Cost	Fee	Cost (Ave)	Fee (Ave)
1998	1,129,572	\$39,386,495	\$36,206,613	\$4,743,512	\$32.05	\$4.20
1999	1,157,292	\$45,502,068	\$42,268,413	\$4,919,046	\$36,52	\$4.25
% Change	2%	16%	17%	4%	· 14%	1%



Once a drug patent has expired, generic manufacturers frequently begin producing similar drugs that are generally much cheaper. When three or more generics of a drug are available, HCFA sets a federal upper limit on the cost of these drugs. Medicaid programs use this upper limit as the MAC price and apply this price to all products regardless of manufacturer. (For example, all acetaminophen 400 mg tablets will have the same MAC price regardless of which company produces them.) This methodology encourages pharmacies to use generics since they will receive the same reimbursement for brand and generic products. The only exception occurs if the prescriber writes "Brand medically necessary" on the prescription; then the pharmacy will receive the brand price for the brand product. Generic manufacturers are no less profit-driven than other manufacturers and have participated in efforts to limit competition and drive up costs. In 1998, one generic company cornered the market on a basic ingredient for many of the anti-anxiety medications forcing other companies to cease production. The generic company then increased the price on these products, sometimes by 1000%. Nothing pays as well as a monopoly.

The local pharmacy acquires its drugs through wholesalers and has limited control over which products are available. Perhaps surprisingly, pharmacy profit margins are generally greater on generic products than brand name products. A 1996 report by the Office of Inspector General estimated that overall in Montana, the AWP exceeded invoice prices by 16.2 percent for brand name drugs and 48.5 percent for generic drugs. Since Medicaid pays AWP less 10% for brand name drugs and MAC prices for generic drugs, the margins cited by the OIG do not translate into that level of profit for pharmacies.

#### Claims Processing

Since September 1994, prescription drug claims have been adjudicated through Consultec's pharmacy benefit manager, PDCS. Over 95% of each year's million plus drug claims are processed on-line in real time. Through Consultec we have the advantage of a sophisticated system that allows the program to manage the pharmacy benefit in the same way private PBM's operate.

#### **Drug Utilization Review**

The program's drug utilization review process includes both a prospective and retrospective review. Prospective review occurs during claims processing. This review screens for potential drug therapy problems due to therapeutic duplication, drug-disease contraindications, drug-drug interactions, incorrect drug dosage or duration, drug-allergy interactions, and clinical abuse/misuse. The system also controls duplicate billing and early refills by members.

Montana Medicaid contracts with the Mountain-Pacific Quality Health Foundation and The University of Montana School of Pharmacy to provide the retrospective review function. The Foundation uses a software program from Pharmark that reviews drug and medical claims data on a monthly basis in order to identify patterns of inappropriate or medically unnecessary care by pharmacists, physicians, and patients. The Drug Use Review (DUR) Board, comprising three pharmacists and three physicians, meet on a regular basis to review

patient profiles and identify drug therapy patterns for intervention or education. The Foundation provides ongoing educational outreach programs to educate practitioners on common drug therapy problems with the aim of improving prescribing or dispensing practices.

In addition to the prescription drug program's review, drug review occurs in nursing facilities as part of their certification requirements. Nursing facilities are required to have residents' drug regimens reviewed by a pharmacist on a monthly basis.

#### Drug Formulary

A drug formulary is a listing of products eligible for coverage under a particular prescription drug benefit. Use of drug formularies is a common strategy by insurers to control prescription costs. Because of OBRA 1990, Medicaid programs cannot use formularies like other insurers to cover only preferred products. The program is allowed to limit access to drugs, however, if the state has a prior authorization system. Montana Medicaid contracts with the Mountain-Pacific Quality Health Foundation to operate its drug prior authorization program. The Foundation has licensed pharmacists staffing the program.

Montana Medicaid has limited access to certain drugs since 1994 and continually reviews the formulary for changes. Drugs considered for restriction undergo review by the DUR Board with information provided by The University of Montana School of Pharmacy. The Board also recommends criteria used for prior authorization. Drugs recommended for restriction must have no significant, clinically meaningful therapeutic advantage, in terms of safety, effectiveness, or clinical outcome, over other drugs evaluated and recommended for inclusion in the formulary. Drugs are not restricted solely because of their cost. The current list of restricted drugs and their criteria is described in a separate section.

#### **Drug Rebate**

Montana Medicaid has participated in the federal drug rebate program since 1991. Based on information from manufacturers, HCFA sets the rebate amount on each drug NDC. The Department invoices approximately 400 manufacturers quarterly and tracks payments. Manufacturers' rebates have consistently amounted to about 20% of drug expenditures.

In September 1999, a new drug rebate analysis and management system (DRAMS) was implemented. This system will improve the rebate process by ensuring that invoices are more accurate thus reducing the number of disputes with manufacturers. The system also provides a mechanism for tighter monitoring of providers and their billing procedures and has resulted in significant recoveries from providers who have billed incorrectly. The most recent recovery of \$108,960 was paid in November for incorrect billing of one drug for one patient over a three-year period.

#### PHARMACY PROGRAM EXPENDITURES & REBATE SUMMARY November 8, 1999

Fiscal Year	Program Expenditure <sup>1</sup>	Rebates Received <sup>2</sup>	% of Expenditure
1997	\$33,023,333	\$6,359,626	19.26
1998	\$36,841,203	\$7,097,750	19.27
1999	\$42,149,314	\$8,842,631	20.98

<sup>&</sup>lt;sup>1</sup>Claims paid through June 30

<sup>&</sup>lt;sup>2</sup>Rebates received through June 30

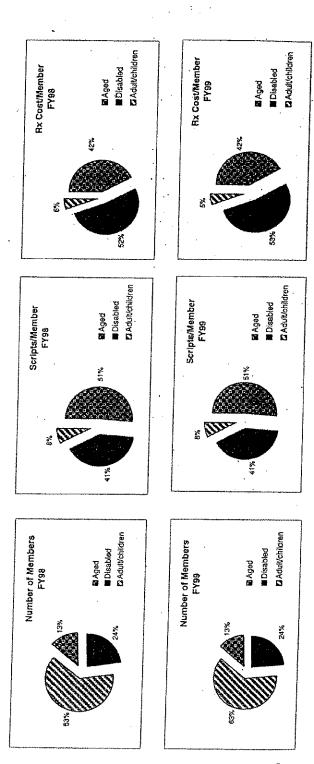
#### Who Uses the Prescription Drug Program?

Medicaid recipients who are elderly or disabled have received 92% of all prescriptions paid through the prescription drug program in fiscal years 1998 and 1999. Members 65 years and older received 55% of all prescriptions while members 19 years or less received 8% of the prescriptions for these two years. Analyses of use by members are shown in the following pages.

An analysis of drug therapeutic classes shows that the top 12 classes in terms of number of scripts and payments are for drugs used to treat chronic diseases. These top 12 classes account for about 48% of all scripts and 53% of the expenditures during the time period analyzed.

DRUG EXPENDITURES - MEMBER PROFILE FY1998 & FY1999

			***************************************	285 L	11338 & FY1939	on:					
Eligibility Group	# Utilizing Members	1998 # Utilizing # Prescriptions Net Payment Scripts/ RxCost/ Members Member	1998 Nei Payment s	Scripts/ Vember	RxCost/ Member		Utilizing A	# Prescriptions	# Utilizing # Prescriptions Net Payment Scripts/ Members	it Scripts/	RxCost/
Anad									c	Nerriber	Member
Disabled	4,006	358,576	\$10,251,363	44.8	\$1,280.46		7,965	364,558	\$11,623,590	45.8	C+ 150 22
Adult/children	38,304	262.908	\$22,527,426		35.7 \$1,582,76		14,409	533,542			37.0 \$1,855.61
	***************************************		130,100,00	٠l	9172,50		37,199	258,994	\$7,139,045		\$191.91
Totals	59.960	1 129 570	129 570 430 306 446	20.7							
			01+10001200	, O	\$50£.88		58,990	1,157,194	\$45,500,054	19.6	\$771.39
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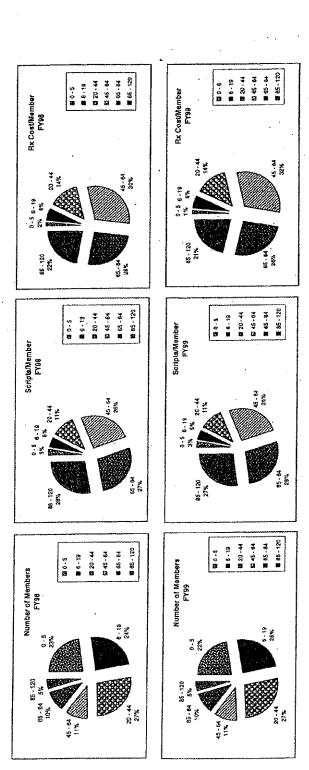
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Drug Expenditures by Age & Gender FY1998 & FY1999

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		2005	2		23.			7/1/98-6/30/99	99		
AGE	Utilizing Members	Number of Prescriptions	Net Payment	Rx's per Member	Cost per Member		Utilizing	Number of	Net Payment	Rx's per	Cast per
Male								rescriptions		метрег	Member
က (၀	7,160	35,615	\$644,645	4,97	\$90.03		6.958	34 408	955 A78		
6 - 19	7,127	66,790	\$2,821,408	48.0	€		4,000	oot to	004,000		
20 - 44	4.398		\$4 085 086	30.00	Ġ		100	00, 00	43,077,106		
45 - 64	VOV C		707 700 64	20.00			4,385	92,463	\$5,768,168	21.09	\$1,315.43
. 53 . 53	† 6 † 1 † †		43,254,131	32,24			2,607	86,381	\$3,896,927	33.13	\$1,494.79
85, 190	10/,1	- 1	\$2,063,157	39.10			1.673		\$2,181,061	39.30	
1	CAC	22,546	\$645,170	38.19	\$1,087.98		578	22,655	\$710,716	39.20	\$1,229.61
Totals	22,999	364,894	\$14,413,596	15.87	\$626.71		007 00	ľ	100 000 0+4		
		· · · · · · · · · · · · · · · · · · ·		<u>.</u>			K.C., 1 US	010/200	195,282,014	16.20	8/17.44
Female											
0 - 5	6,749	33,131	\$556,259	4.91	\$82.42		6.549	29.891	4510 200	31	
6-19	7,895	49,948	\$1,584,541	6.33	₩,		7.836	100,03 A 1 0 0 1	ė		
20 - 44	12,637	,	\$7.278.175	15.65			1000	104 A			
45 - 64	3,988	*	\$6 010 789	75.75			(2,13)	195, 131	\$8,252,7U5		
65 - 84	4,300	,	45,010,024 45,057,48B	10,70			4, 154	202,122	\$8,677,982		
85 - 120	0.00	•	004, 408,00 408,00	27.04			4,285	204,095	\$6,875,066		
1	2		42,000,004	45.20	\$1,161,11		2,340	105,826	\$2,991,533	45,22	\$1,278.43
Totale	ATO 90	****		l							
0.00	78,00	79,497	\$24,972,899	20.68	\$675.47		36,310	789,479	\$29,209,681	21,74	\$804.45
Total (Mg	Total (Male & Female)	(9)		-	ras Partiki						
0.5	13,908	68,746	\$1,200,905	494	700 300		12 503	200	0000		
6 - 19	15,021	•	\$4,405,948		¥		10,006	•	41,106,607		
20 - 44	17,032	•	\$10.000 E 90 C \$	20.0			0,0,4		\$4,979,102		
45 - 64	6.47g		640 464 040				16,520	287,594	\$14,020,873		\$848.72
. S.	100	•	218,401,014	40.57			6,770	288,503	\$12,574,909	42,61	\$1,857.45
200	6000		\$6,020,645 \$6,020,645	43.85			5,957	269,838	\$9,056,127	45.30	\$1,520,25
. 1	2,900	127,190	\$3,330,823	43.77	\$1,146.19		2,917	128,481	\$3,702,249	44.05	
Testala		ı									
totals	09,86U	1,129,571	\$39,386,495	18.84	\$656.88		59,006	1,157,289	\$45,502,068	19.61	\$771.14
						Ŷ					

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Drug Expenditures by Age & Gender FY1998 & FY 1999



# Comparison of Utilization and Costs TOP THERAPEUTIC CLASSES

Analgesics: Pain treatment

Anti-depressants, Anti-anxiety & Anti-psychotics: Mental Illness

Anti-uicer: Gastroesophagel reflux disease (GERD); duodenum or gastic ulcers

Beta-adrenergic: Asthma treatment

Anti-Inflammatory: Rheumatoid arthritis, pain, inflammation, fever Diuretics, Hypotensives, Calcium channel blockers: High blood pressure and coronary disease

Antihistamines: Allergies

Anti-convulsants: Seizures, epilepsy

#### Cost Trends

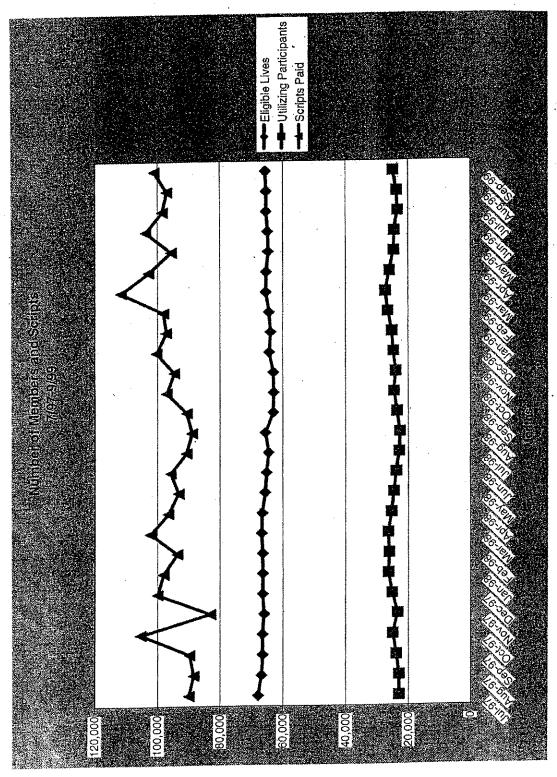
An examination of the drug expenditures over the last 18 months shows that the number of eligible members and the number of utilizing members have remained relatively stable. The number of prescriptions has increased over this time period, although not dramatically. The dramatic increase in drug expenditures from about \$3 million per month to almost \$4.5 million per month is reflected in the cost of scripts per utilizing member. The average cost in these scripts has increased from about \$130 to \$180. This increase is shown in the analysis of drug therapeutic classes. Comparing utilization and costs for the most recent quarter (7/1-9/30) to the same time period in 1998 shows that utilization increased by 9.7% and the cost per claim increased by 15.7% in the most recent quarter.

Although these cost increases are unfortunate, they are not unexpected. All health programs that cover prescription drugs are experiencing similar increases, including Medicaid programs in other states. The greater reliance on drug therapy, however, has resulted in lower costs in other programs, especially hospital and nursing home costs.

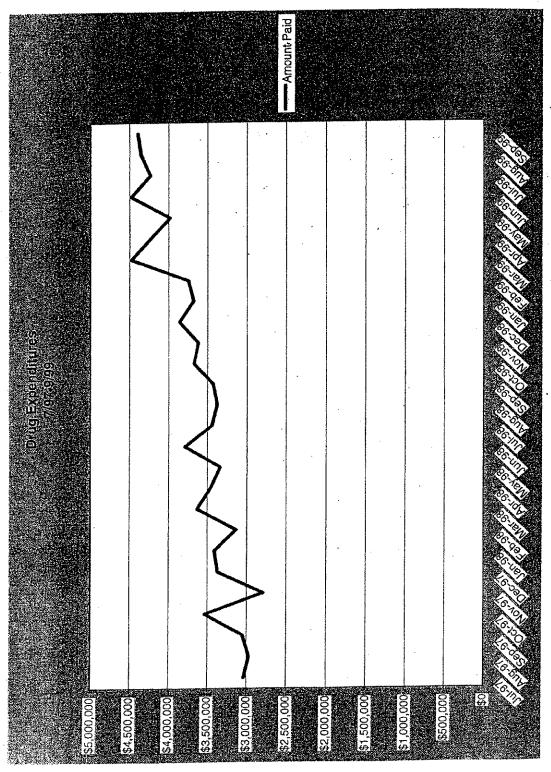
Pharmacoeconomic studies have repeatedly shown the cost benefit of using drug therapy and thereby avoiding other healthcare costs. For example, a 1998 study of the cost-effectiveness of clozapine for severe psychosis showed that hospitalization time decreased from 47.7±59.8 days per patient per year prior to clozapine treatment to 4.6±11.3 days after clozapine treatment. Cost savings from reduction in hospital days were estimated to be \$23,650 per patient per year. (Ghaemi SN, Ziegler DM, Peachey TJ, et al.)

# DRUG EXPENDITURES 7/1997 - 9/1999

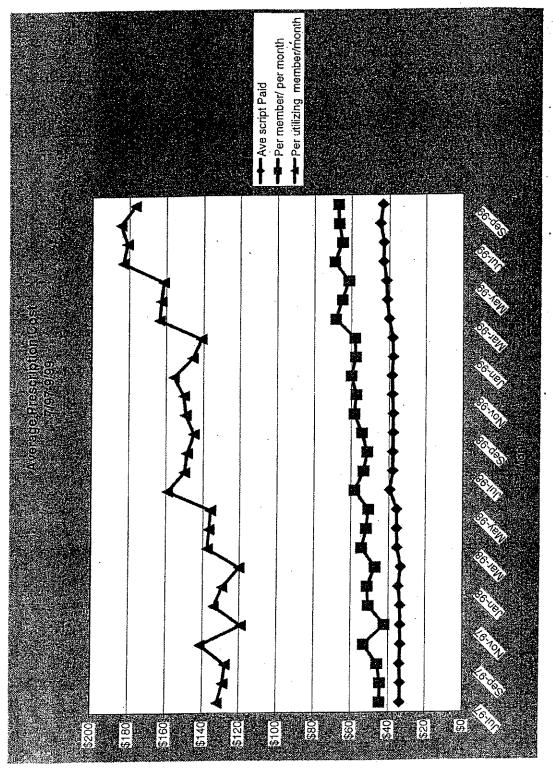
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Per utilizing member/month	\$131.87	\$128.96	\$127.74	\$141.51	\$119,17	\$133.96	\$129.50	\$120.10	\$137.71	\$136.83	\$135,96	\$159,13	\$150.09	\$148.77	\$145,14	\$149.56	\$150.56	\$155,90	\$145.90	\$141.18	\$163.73	\$162,77	\$161.52	\$183.12	\$180.98	\$184.38	\$176.75
Per member/ per month	\$44.70	\$44.49	\$45.92	\$53,10	\$42.28	\$50.72	\$51.36	\$47.21	\$54.40	\$51.94	\$50.85	\$58.09	\$53.31	\$51,53	\$54.32	\$58.35	\$57,41	\$59.96	\$57.65	\$58.13	\$68.42	\$64,90	\$61.51	\$69.07	\$64,87	\$66.75	\$67.06
Ave # Scripts Util Members	3.91	3.84	3.75	4.22	3.55	3.98	3.73	3.59	3.87	3.82	3.80	4.02	3.96	3.92	3.84	3.95	3.94	4.05	3.85	3.70	4.08	3.95	3.88	4.24	4.21	4.10	4.06
Ave # Scripts Elig members	1.33	1.32	1.35	1.58	1.26	1.51	1.48	1.41	1.53	1.45	1.42	1,47	1,41	1.36	1.44	1.54	1.50	1.56	1.52	1.52	1.70	1.57	1.48	1.60	1.51	1,49	1.54
Ave script Paid	\$33.74	\$33.60	\$34.02	\$33.53	\$33.60	\$33,69	\$34.75	\$33.48	\$35,55	\$35,80	\$35.80	\$39.54	\$37.92	\$37.97	\$37.80	\$37.84	\$38.25	\$38.46	\$37.88	\$38.18	\$40.14	\$41.24	\$41,63	\$43.18	\$43.03	\$44.93	\$43.55
Amount Paid	\$3,035,758	\$2,973,880	\$3,053,398	\$3,532,809	\$2,790,489	\$3,369,764	\$3,408,819	\$3,135,678	\$3,631,998	\$3,457,074	\$3,337,435	\$3,786,267	\$3,440,699	\$3,377,628	\$3,426,526	\$3,672,505	\$3,618,306	\$3,856,754	\$3,681,257	\$3,744,762	\$4,477,901	\$4,240,043	\$3,980,003	\$4,478,455	\$4,238,087	\$4,361,034	\$4,397,874
Scripts Paid	89,984	88,503	89,748	105,362	83,053	100,013	98,100	93,670	102,159	96,556	93,224	95,758	90,730	88,957	90,648	97,057	94,607	100,290	97,187	98,089	111,553	102,812	95,611	103,710	98,489	97,064	100,987
Utilizing Participants	23,021	23,061	23,904	24,965	23,417	25,155	26,322	26,109	26,375	25,266	24,547	23,793	22,925	22,703	23,608	24,556	24,032	24,738	25,231	26,524	27,350	26,050	24,641	24,456	23,418	23,652	24,882
	67,907	66,846	66,497	66,536	66,005	66,440	698'99	66,424	292'99	66,556	62,629	65,182	64,540	65,544	63,084	62,940	63,023	64,320	63,860	64,416	65,448	65,331	64,705	64,843	65,333	65,332	65,586
Payment Month	76-jnf	Aug-97	Sep-97	Oct-97	Nov-97	Dec-97	Jan-98	Feb-38	Mar-98	Apr-98	May-98	96-unf	Jul-98	Aug-98	Sep-98	Oct-98	Nov-98	Dec-98	Jan-99	Feb-99	Mar-99	Apr-99	May-99	66-unf	Jul-99	Aug-99	Sep-99



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#### **Factors in Increased Program Cost**

Several articles are enclosed that address the various factors affecting the increased cost of prescription drug programs. These factors range from new drug therapies with higher prices, an aging population with more chronic illnesses, and direct-to-consumer advertising by the pharmaceutical industry.

#### **Program Initiatives**

Tab-splitting: For some medications, the cost of a low strength tablet is the same as for a higher strength tablet. Beginning January 15, we will implement a policy requiring that only the higher strength tablet of some medications be dispensed, and the patient will be advised by the pharmacist to split the tablet to get the proper dose. Such a program is currently being used by Blue Cross Blue Shield and the Washington Medicaid program.

Formulary:

The program continues to evaluate new drugs as they come to market and determine whether or not access should be restricted. Drug use patterns are also evaluated on a continuing basis and restrictions are implemented when problems become evident.

The program will evaluate using a tiered system of Tiered system of Reimbursement: reimbursement that differentiates chain, independent and nursing home pharmacies.